

November 26, 2019

U.S. Environmental Protection Agency
Document Processing Desk (Distribution Code)
Attn: Jeannine Kausch, Product Manager 92
Office of Pesticide Programs (7504P)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Dear Ms. Kausch:

Better Air International Limited has developed a microbial pesticide control agent (MPCA) composed of *Bacillus subtilis* and *Bacillus amyloliquefaciens* spores (specifically *Bacillus subtilis* Strain 3, *Bacillus subtilis* Strain 281 and *Bacillus amyloliquefaciens* Strain 298). The end product, EB-8™, is a 1:1:1 mixture in a [REDACTED]. This product is for indoor, non-food use only, principally for the control of bacteria and molds that may cause undesirable odors and surface discoloration. EB-8™ will be dispersed in residential and commercial establishments by use of proprietary devices, sold only by Better Air. These devices programmed to apply EB-8™ periodically as a fine mist at the label rate. Use manuals, included with the draft master label, provide detailed instructions on the operation of these devices.

Prior to initiating our testing program, representatives of Better Air and Intertek met with EPA in April of 2017 to describe the product and receive agency input on testing procedures. EPA agreed at that time that we might use the mixture as the test substance in our testing program in lieu of testing each individual strain.

The major toxicology tests required for MPCA registration are Acute oral toxicity/pathogenicity, Acute pulmonary toxicity/pathogenicity and Acute injection toxicity/pathogenicity. EPA test guidelines require the use of technical material for these tests. The commercial end product (EP) is a mixture of 3 bacillus strains but there is, in a sense, no actual or independent technical material. The 3 individual strains have no other use than to be mixed and the individual strains are stored only for short periods before being mixed together. For the purposes of this testing, therefore, we had the toxicology laboratory make a mixture of the three strains at the highest attainable concentration (~10⁹ CFU/ml) so that test animals would receive a dose of each of the 3 strains to conform to agency dose level requirements. This mixture we have labelled the technical material or TGAI.

The manufacturing process for EB-8™ is straight forward. [REDACTED]

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment



It is useful to understand our selections for the test material for product chemistry. Where only TGAI was required, we tested the TGAI, discussed previously, that was prepared at the toxicology laboratory. For storage stability, there is no manufacturing use product (MP) or independent TGAI, therefore, just the end product is being tested for long-term stability. A 12-month test is in progress at Stillmeadow laboratory and at the 6-month point has been shown to be stable. No miscibility testing was done because the end product is in a ready to use form and is not an emulsifiable concentrate. Corrosion is being done on the EP (as part of the storage stability test). Viscosity was done only on EP as there is no MP. The major difference between the “TGAI” and EP is the EP contains [REDACTED]. Both are [REDACTED] and can reasonably be expected to have identical product chemistry.

The oral, inhalation and injection toxicity and pathogenicity tests mentioned previously have not shown adverse effects. Similarly, the eye and dermal irritation tests did not show irritation and a sensitization test (Buehler protocol, as recommended by EPA via email, 7/31/2019) did not show an allergenic response. Based on these results, we believe the appropriate cautionary statement is the warning to Keep Out of Reach of Children and a Hot line number for calling a poison control center. We note that this is consistent with labeling approved for Velondis™ Plus, EPA Reg. No. 71840-EA, which is also composed of *Bacillus subtilis* and *Bacillus amyloliquefaciens*.

The end product is provided to homeowners and commercial facilities in ready to use cartridges that require minimal handling and present negligible exposure risks. As such, we do not believe personal protection equipment is necessary. The agency has adopted similar labeling for indoor products such as Raid Ant & Roach Killer 17 (EPA Reg. No. 4822-447).

To support the safety of the use of EB-8™, Intertek evaluated air concentrations and inhalation exposure of the *Bacillus* spores in residential rooms using the EPA IAQX model. Air exchange rates in the model were based on the research of the National Exposure Research Laboratory, U.S. Environmental Protection Agency. The *Bacillus* spore release rate from the spray machine was at the label rate. The model predicts that air concentrations will reach a steady state concentration within one day, ranging from 1.34E+4 to 2.88E+4 CFU/m³. Based on EPA mean adult inhalation rates, cumulative daily doses of EB-8™ would range from 2.1E+5 to 4.6E+5 CFU/person. Such exposures are a small fraction (0.13% - 0.29%) of the intratracheal dose (1.61E+8 CFU) used in the Acute Pulmonary Study with EB-8™. In the pulmonary study, no adverse health effects were observed, and no abnormalities recorded in the post-exposure necropsy. The results of our inhalation exposure and safety evaluation support the conclusion that EB-8™ used as directed poses negligible risks of adverse health effects.¹

¹ Details of this assessment are provided in the Waiver Request for Acute Inhalation Toxicity for EB-8™ EP included in this submission.

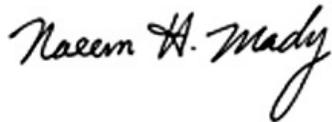
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Regarding the data matrix, as indicated previously we have conducted toxicology and chemistry studies only on the mixture of the 3 bacillus species. There exist no data on the individual species and, we understood from our meeting with the agency, this was an acceptable approach. As a result, we are providing with the submission a single data matrix covering the various tests conducted with the mixture. A matrix could be prepared for each of bacillus species but it would just be a repetition of the same data and this approach would not seem to provide useful information.

Finally, for most of the period when testing was being conducted, the test material was identified as Enviro-Biotics™ TGAI or Enviro-Biotics™ EP. EPA recently informed us that the name Enviro-Biotics™ might be problematic and not meet with agency approval. As a result, we have recently changed the name to EB-8™. Reviewers should be aware that EB-8™ and Enviro-Biotics™ are synonymous and refer to the same substance. Better Air desires to retain the name Enviro-Biotics™ and, therefore, in this submission we ask the agency to consider the alternative trade names of Enviro-Biotics™ and E-Biotics.

Should you have any questions, please contact the undersigned at (201) 952-8110, or via email at: naeem.mady@intertek.com.

Sincerely yours,

A handwritten signature in black ink that reads "Naeem A. Mady". The signature is written in a cursive style with a large, stylized initial 'N'.

Naeem Mady
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